

## **END MEMBER FOR A BONE FUSION IMPLANT**

### Cross-Reference to Related Applications

5 Priority of Provisional Application no. 60/118,806 filed on February 4, 1999 is claimed under 35 U.S.C. § 119(e).

### Field of the Invention

10 The present invention relates to a device for bone fusion, and in particular to an end member for a bone fusion implant.

### Background of the Invention

The treatment and management of bone defects remains one of the most challenging aspects of orthopaedics. Bone defects occur in a wide variety of clinical situations.

15 Restoring natural anatomical length and shape of any long bone with a bone defect is problematic. Additionally, whenever a vertebra has to be removed, it is necessary to insert a vertebral spacer to restore the natural length and curvature of the spine as well as to promote bone fusion. Restoring spinal anatomy and stability and promoting bone fusion are even more difficult in a corpectomy, a surgical procedure in which a section of one or 20 several vertebrae is removed.

Many different implants have been developed for use with bone defects. So-called “mesh implants” have shown to be particularly effective. One such implant is the SynMesh™ available from Synthes (USA) of Paoli, Pennsylvania. The SynMesh™ is a titanium mesh cylinder which is provided with a plurality of uniformly-spaced apertures of 25 uniform size distributed on its surface. In order to address the different clinical situations in which bone defects arise, the SynMesh™ is available in a variety of lengths and diameters. Commercially available allografts for treating bone defects have recently become available.

Although the clinical results of mesh and allograft implants have generally been positive, one possible clinical complication is subsidence of the implant. Excessive sinking 30 of the ends of the implant into the bone with which they contact is especially troublesome whenever the bone is extremely porous. From both a mechanical and physiological point-of-view, it would also be advantageous to increase the surface contact area between the implant and bone. U.S. Patent No. 5,702,451 to Biedermann *et al.* discloses end rings that attempt to address these concerns. However, the end rings disclosed have no provisions for 35 holding, insertion, and distraction instruments. Thus, implantation can be difficult.

Furthermore, there can be excessive movement between the bone and the disclosed end rings after implantation. This may delay, and perhaps prevent bone fusion.

As the discussion above illustrates, there is a need for an improved end member for use with a bone fusion implant.

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### Summary of the Invention

The present invention relates to an end member for use with a bone fusion implant for fusing portions of bone. The end member has a first portion, a second portion sized to be inserted into the bore of the implant, and a shoulder between the first and second 10 portions. When the second portion is inserted into the bore, the shoulder rests on an edge of the implant. The top surface of the first portion conforms in size and shape with the bone and has a channel or multiple channels for receiving a surgical instrument. When multiple channels are present, all the channels can run in the same direction, (e.g. the channels run in the anterolateral direction), or the channels can run in different directions, (e.g. a first 15 channel runs in the anterior-posterior direction and a second channel runs in the lateral direction).

If the implant is made of metal, the end member is made of the same material in order to resist corrosion. The end member may also be made of allograft bone. The end member may have a wedge-shaped or spherical profile to restore the natural curvature of 20 bone or to correct for a non-orthogonal osteotomy. One way to create the wedge-shaped profile is to have the first end of the first portion to be thicker than the second end.

The top surface can be made in any suitable cross-sectional shape, such as oval, oblong, or round, and may be annular or solid. The top surface can be a flat planar surface or can have a curvature that mimics the topography of the bone. The top surface may be 25 provided with teeth or textured for interlocking with the bone. The teeth may have a pyramid or saw tooth shape.

In order to secure the end member to the implant, the second portion may have a hole for receiving a fastener. Alternatively, the exterior surface of the second portion may have protuberances that are sized to fit within the apertures of the implant. In an exemplary 30 embodiment, the second portion comprises a plurality of tabs to secure the end member to the implant. These tabs may be resilient so that the tabs flex inward upon insertion of the second portion into the implant and flex back outward to create a friction fit that secures the end member to the implant. In another embodiment, the end member includes a projection hinged or pivotably connected to the first portion, a threaded bore in the second portion, and 35 a set screw insertable into the threaded bore. Threading the set screw into the bore causes outward movement of the projection to thereby secure the end member to the implant.

In an alternative embodiment, an end member according to the present invention includes a top surface conforming in size and shape with the bone and a sleeve extending from the top surface and configured and dimensioned to receive an end of the implant. The end member further comprises first and second portions pivotable between and open 5 position to facilitate receiving the end of the implant by the sleeve and a closed position to secure the end member to the implant. A locking element fixes the end member in the closed position.

In another alternative embodiment, the end member includes an outer ring having a prong with a ramped surface and an inner ring rotatable with respect to the outer ring. The 10 inner ring has a protrusion which contacts the ramped surface of the prong upon rotation to thereby urge the prong radially outward.

#### Brief Description of the Drawings

Preferred features of the present invention are disclosed in the accompanying 15 drawings, wherein similar reference characters denote similar elements throughout the several views, and wherein:

FIG. 1 shows a perspective view of a first embodiment of an end member according to present invention;

FIG. 2 shows a side view of the end member of FIG. 1 inserted into a cylindrical 20 mesh implant;

FIG. 3 shows a perspective view of an end member having an oblong shape;

FIG. 4a shows a perspective view of an end member having an oblong shape and teeth for improving implant stability;

FIG. 4b shows a perspective view of an end member having first and second slots 25 for facilitating use with implantation instrumentation;

FIG. 4c shows a perspective view of another embodiment of an end member having first and second slots;

FIG. 5 shows a side view of an end member having a wedge-shape profile;

FIG. 6 shows a perspective view of an end member having protuberances for 30 fixation to the implant;

FIG. 7 shows a perspective view of a non-annular end member;

FIG. 8 shows a perspective view of the bottom of an end member according to the present invention;

FIG. 9 shows a perspective view of the bottom of an end member according to the 35 present invention;

FIG. 10 shows a top view of another embodiment of the end member according to the present invention;

FIG. 11 shows a cross-sectional view of the end member of FIG. 10;

5 FIG. 12 shows a top view of another embodiment of the end member according to the present invention;

10 FIG. 13 shows the end member of FIG. 12 secured to a cylindrical mesh implant; and

15 FIG. 14 shows a cross-sectional view of another embodiment of the end member according to the present invention.

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#### Detailed Description of the Preferred Embodiments

15 FIG. 1 shows a first embodiment of an end member 10 according to the present invention. End member 10 has a first portion 12 and a second portion 14. As first portion 12 is larger than second portion 14, a shoulder 16 is formed at the intersection between first and second portions 12, 14. A top surface 18 of first portion 12 is provided with a first slot 20 for accommodating surgical instrumentation such as holding, insertion, and/or distraction instruments. Top surface 18 is shown in FIG. 1 with a round shape. However, as will be evident from the other embodiments, top surface 18 can have any suitable shape. Preferably, top surface 18 has a shape that matches the shape of the bone it will contact.

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25 Second portion 14 is also shown having a round shape. As was the case for top surface 18, second portion 14 can have any suitable shape. Preferably, the shape of second portion 14 matches the shape of the bone fusion implant used with the end member. As best seen in FIG. 2, second portion 14 is sized and shaped to be inserted into the inner bore of a bone fusion implant 22 so that shoulder 16 rests on bone fusion implant 22. Bone fusion implant 22 can be a number of different implant types, including, for example, a mesh implant, an allograft implant, or any metallic or non-metallic implant. If implant 22 is made of a metallic material, end member 10 is preferably made of the same metallic material or a non-metallic material to avoid mixed-metal (galvanic) corrosion. End member 10 can also be made of allograft bone from cancellous bone, cortical bone, a combination of cancellous and cortical bone, or a composite of cancellous and cortical bone. After 30 implantation of end member 10 and bone fusion implant 22, physiological compressive forces will tend to hold end member 10 in place against bone fusion implant 22. However, to provide further stability as well as to facilitate pre-operative and intra-operative handling, second portion 14 can be secured to bone fusion implant 22. For example, second portion 35 14 can be press-fit or snap-fit into bone fusion implant 22. Additionally, because bone fusion implant 22 is typically deformable, bone fusion implant 22 can be crimped to end

member 10. Second portion 14 can also be provided with a hole 24 for receiving a fastener such as a pin or a screw. End member 10 is inserted into bone fusion implant 22 so that hole 24 aligns with one of apertures 26 on bone fusion implant 22. Hole 24 can extend either partially or completely through second portion 14 and can be threaded. As shown in 5 FIG. 6, second portion 14 can alternatively have protuberances 28 that are sized to fit in apertures 26 for mechanically securing the end member to the bone fusion implant. Other exemplary mechanisms for securing the end member to the bone fusion implant are described in more detail below

Referring back to FIGS. 1 and 2, the surface area of top surface 18 is greater than the 10 surface area of the top and bottom surfaces of bone fusion implant 22. Because of this greater surface area, there is more contact area between top surface 18 and the surrounding bone than there would be for the top and bottom surfaces of implant 22. The increase in contact area helps to resist subsidence of implant 22. The increased contact area has other benefits such as greater load sharing between end member 10 and the surrounding bone. 15 Top surface 18 is shown as a ring with an annular space 30. New bone can form in annular space 30 to promote fusion. Annular space can be filled with bone chips or any other osteoinductive or osteoconductive material to promote the formation of bone. Alternatively, as shown in FIG. 7, top surface 18 can be a solid surface to maximize contact 20 area between top surface 18 and the surrounding bone. A solid top surface 18 would be desirable in clinical situations in which subsidence is especially a concern.

FIG. 3 shows a second embodiment of an end member 110 according to the present invention. In general, most of the structure of end member 110 (as well as the embodiments described below) is like or comparable to the structure of end member 10 and, accordingly the same reference numeral is used for like components and discussion of those like 25 components is not believed necessary. End member 110 has an oval or oblong shape and would be used in situations in which the surrounding bone (and consequently the bone fusion implant) is substantially oval or oblong. When the end member has a non-symmetrical shape like end member 110, first slot 20 can be provided in any orientation. For example, first slot 20 is shown running along the long axis of end member 110, but 30 could run in any direction to be oriented differently with respect to the surrounding bone. The variability in the placement of first slot 20 means that first slot 20 can be positioned as best suited for the particular surgical approach that is being used. Specifically, if end member 110 is being implanted with the short axis in the anterior/posterior direction, then first slot 20 is ideal for a lateral surgical approach. If an anterior or posterior approach is 35 anticipated, then first slot 20 should run in the anterior-posterior direction.

FIG. 4a shows an end member 210 with first slot 20 running at an angle with respect to the long axis of end member 210. This direction of first slot 20 is preferred for an anterolateral surgical approach, which can be used in spinal surgery. FIG. 4b shows an end member 212 that includes first and second slots 20, 21, both running at an angle with respect to the long axis of end member 212. Preferably, first and second slots 20, 21 are symmetrically placed with respect to the long axis of end member 212. Providing end member 212 with both first and second slots 20, 21 allows at least one of first and second slots 20, 21 to be accessed during implantation regardless of whether the left or right side is used for the anterolateral surgical approach. Furthermore, the arrangement of slots 20, 21 allows one end member to be used on each end of bone fusion implant and still have the slots on the top end member align with slots on the bottom end member. FIG. 4c shows an end member 214 that also includes first and second slots 20, 21. First slot 20 runs parallel to the long axis of end member 214 and second slot 21 runs transverse to the long axis of end member 214. Including both first and second slots 20, 21 on end member 214 provides access to at least one of first and second slots 20, 21 regardless of the implantation orientation of end member 214 or the surgical approach.

For each of the end members shown in FIGS. 4a, 4b, and 4c, top surface 18 has a plurality of teeth 32 which provides a mechanical interlock between the end member and the surrounding bone. Teeth 32 provide the mechanical interlock by penetrating the bone. The initial mechanical stability afforded by teeth 32 minimizes the risk of post-operative pullout or expulsion of the end member. Teeth 32 can have any suitable configuration such as pyramid-shaped, saw-tooth shaped, etc. Alternatively, top surface 18 can be textured to provide the mechanical interlock between the end member and the surrounding bone.

As seen in FIG. 5, an end member 310 has a wedge profile. A wedge profile would be useful in spinal applications in order to restore the natural curvature of the spine or any bone. A wedge profile would also be useful to compensate for a non-perpendicular osteotomy cut dictated by the pathology, clinical situation, or erroneously made to remove bone. It should be noted that as an end member would ordinarily be used on each end of bone fusion implant, end members having different wedge profiles can be used together. One way to achieve this wedge shape results from a gradual decrease in thickness in first portion 12 from a first end 34 to a second end 36 so that top surface 18 has a slope defined by angle  $\alpha$ . In FIG. 5, top surface 18 is shown as a flat planar surface. However, top surface 18 can be a curved surface and still retain the wedge-shaped profile. As the curve can be made to be a mirror-image of the topography of the vertebral end plates, a curved top surface 18 would conform to the contours of the vertebral end plates.

As previously discussed, FIG. 6 shows an end member 410 that is provided with protuberances 28 sized to fit in apertures 26 of bone fusion implant 22 (FIG. 2). FIG. 7, which has also been discussed, shows an end member 510 having a solid top surface 18 that is preferably used when there is a higher incidence of subsidence.

5 FIG. 8 shows an end member 610 that has a second portion 14 that includes a plurality of tabs 40 for securing end member 610 to bone fusion implant 22. In one embodiment, tabs 40 are resilient so that as second portion 14 of end member 610 is pushed into bone fusion implant, tabs 40 flex inward and then back outward to secure end member 610 to bone fusion implant 22. As bone fusion implant 22 has some elasticity which would 10 allow it to flex outward to accept tabs 40, tabs 40 need not be resilient. The number, size, and arrangement of tabs 40 can be varied. FIG. 9 shows an end member 710 that is similar to end member 610 except for the overall change in shape (from round to oval or oblong).

FIGS. 10 and 11 show an end member 810 that has another mechanism for securing end member 810 to bone fusion implant 22. Specifically, end member 810 is a cap that sits 15 on top of implant 22. End member 810 includes a top surface 812 conforming in size and shape with the bone and a sleeve 814 extending from top surface 812. Sleeve 814 is configured and dimensioned to receive a portion of implant 22. In order to facilitate insertion and removal of end member 810 from implant 22, end member 810 is preferably made in two portions 816, 818. In an exemplary embodiment, portions 816, 818 are 20 pivotably connected at a pivot 820 so that portions 816, 818 can be separated, *i.e.* end member 810 opens. End member 810 also includes a locking mechanism for keeping the two portions 816, 818 in contact. In one embodiment, this locking mechanism comprises a first serrated edge 822 that cooperates with a second serrated edge 824.

FIGS. 12 and 13 show an end member 910 that includes inner and outer rings 912, 25 914. Inner ring 912 can be rotated relative to outer ring 914. Inner ring 912 has means for receiving a tool to rotate inner ring 912 (shown as holes 916 that accept prongs of the tool). Inner ring 912 also has a pair of protrusions 918 that cooperate with flexible prongs 920 located on outer ring 914. As inner ring 912 is rotated, protrusions 918 contact prongs 920 and force prongs 920 out in a radial direction. When end member 910 is fitted in implant 30 22, the outward radial movement of prongs 920 causes prongs 920 to press against implant 22 to secure end member 910 to implant 22.

FIG. 14 shows an end member 950 in which second portion 14 includes at least one projection 952. Projection 952 is pivotably connected to second portion 14 at junction 953 so that as a set screw 954 is screwed into threaded bore 956, set screw 954 causes outward 35 movement of projection 952. This outward movement secures end member 950 to implant

22. Junction 953 preferably has a reduced cross section compared to the rest of projection 952 so that the flexing caused by set screw 954 occurs in junction 953.

While various descriptions of the present invention are described above, it should be understood that the various features can be used singly or in any combination thereof.

5 Therefore, this invention is not to be limited to only the specifically preferred embodiments depicted herein.

Further, it should be understood that variations and modifications within the spirit and scope of the invention may occur to those skilled in the art to which the invention pertains. Accordingly, all expedient modifications readily attainable by one versed in the 10 art from the disclosure set forth herein that are within the scope and spirit of the present invention are to be included as further embodiments of the present invention. The scope of the present invention is accordingly defined as set forth in the appended claims.

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